DEC 2 7 2000

K003230

Section 510(k) Premarket Notification Summary (as required by 807.92 (j))

Submitter: Vital Images, Inc.
3300 Fernbrook Lane North –Suite 200
Plymouth, MN 55447-5341
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Date Prepared: October 13, 2000

Contact Person: Robert C. Samec

Device Trade Name: VScore™ with AutoGate option

Device Common Name: Image Processing Software for CT Scanners

Classification Name: 90JAK – CT, Image Processing

Substantially Equivalent To:
VScore Image Processing Software with EKG Signal Gating Option for Cardiac Scoring (K001682)
Vital Images, Inc.

Indications for Use: Cardiac scoring from whole body computed tomography derived measurements. For non-invasive detection and quantification of atherosclerotic plaque.

Device Description: The VScore AutoGate Option for Coronary Artery Calcification Scoring (CACS) is an additional image processing option for K990442 Cardiac Scoring, which was subsequently marketed as VScore™ by Vital Images, Inc. This image processing option allows the operator to select images with reduced motion artifacts when processing data from single or multislice CT Scanners for Coronary Artery Calcification Scoring. The AutoGate option utilizes an image derived motion detection algorithm to select images for review, which were acquired during the asystole of the cardiac cycle.

The cardiac gating function applied to CT coronary Artery Calcification Scoring (CACS) is a productivity tool intended for use by clinicians to identify a subset of CT scan images, taken at or near the cardiac cycle asystole period, to be reviewed to determine the density and location of calcium deposits within the coronary arteries.

A representative cardiac scan will normally contain 350-400 images (slices). The gating function/option normally selects 40-50 of these images, based on their acquisition timing in relation to the motion of the heart. This subset of slices, taken at or near the cardiac cycle asystole period, generally contain little or no motion artifact. The presence of

motion artifact complicates the scoring process/accuracy and is desirable to be reduced/eliminated.

The analysis of the selected slices requires the clinician to individually review the selected slices to determine their suitability for use in determining the patient's total calcium score. The clinician has the ability to review all slices within the total dataset and edit the selection used for scoring based on their clinical protocol for scoring.

Software Development: The software utilized was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

Performance Testing: The AutoGate Option has successfully completed Integration testing/verification.

Clinical Evaluation: Software Beta testing will be successfully completed validating the AutoGate Option prior to market release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Robert C. Samec
Vice President QA/RA
Vital Images, Inc.
3300 Fernbrook Lane North, Suite 200
Plymouth, MN 55447-5341

Re: K003230
AutoGate Option for Cardiac Scoring
Dated: October 13, 2000
Received: October 16, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Samec:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K 003230

Device Name: **AutoGate Option for Cardiac Scoring (K990442)**

INDICATIONS FOR USE:

Intended Use:

Indications for Use: Cardiac Scoring from whole body computed tomography derived measurements. For non-invasive detection and quantification of atherosclerotic plaque.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003230

Prescription Use ✓ OR Over-The-Counter Use)_____
Per 21 CFR 801.109

(Optional Format 1-2-96)